

General Approach to Report Writing in Toxicology

1 Introduction

Reports issued by the Toxicology group summarize analytical findings, and/or provide interpretation of toxicology results. Due to the wide variety of requests and evidence received, this standard operating procedure is only a general guideline for report writing. It will not always be possible to write a report using only the examples provided here. It is acceptable to use other wording as long as the results of the examinations are accurately communicated, a description of the methodology used to reach the results is included, any known limitations are addressed, and the wording is approved by a second qualified toxicology examiner during the technical review process.

Reporting guidelines specified in individual toxicology standard operating procedures will override any guidance in this procedure.

2 Scope

This document provides a guideline for reporting Toxicology results in a consistent manner and applies to Chemistry Unit case working personnel who write toxicology *Laboratory Reports*.

3 Equipment/Materials/Reagents

Not applicable.

4 Standards and Controls

Not applicable.

5 Sampling

Not applicable.

6 Procedure

- a. Before preparing a Laboratory report, prepare a **Results Summary**. This summary should include the tests performed, the dates the tests were performed, the identity of the individual performing the tests, the amount of specimen consumed and the results of each test. If applicable, the interpretation of results based on all of the tests performed will be included in the **Results Summary**. An example of a **Results Summary** is included in Appendix 1.
- b. Prepare and format the Laboratory report in accordance with requirements set forth in the *FBI Laboratory Operations Manual*. Prepare a **Results of Examinations** section, a **Limitations** section, and a **Remarks** section.
- c. The **Results of Examinations** section will be used to communicate the results of the toxicology examinations and a brief description of the methodology used. The **Results of Examinations** section will be consistent with the **Results Summary**. Examples of appropriate wording for the **Results of Examinations** section are included in Appendix 2.
 - For screens such as general alkaline or acid/neutral screens, explain that numerous drugs and metabolites were screened for, and give examples of drugs or drug classes that were ruled out.
 - Include the units of quantitative results. When using an abbreviation for the units for the first time in a report, spell out the abbreviation for clarity.
 - Include the uncertainty value associated with any quantitative result, along with the confidence level and *k* factor.
 - Report uncertainty values to a maximum of two significant figures, with any remainder rounded up.
 - Report measured value to the same decimal place. Determine measured value through truncation. (e.g., 125.5 ± 25.5 becomes 125 ± 26 .)
 - For both positive and negative results, include a description of how the results were obtained (e.g., sample pretreatment, sample extraction and instrumental techniques).
 - Tables may be used to summarize results as long as all applicable elements above are included in the **Results of Examinations** section.
 - Use the word “identified” to report positive results when all of the following apply:
 - Positive results have been obtained in two separate samplings of a biological specimen, or in two specimens from the same person.
 - If screening results or initial testing indicate the presence of a drug, and further testing confirms the presence of the

drug and its metabolite(s), both the drug and its metabolite(s) may be reported as identified. For example, if clonazepam is indicated in an alkaline drug screen, and both clonazepam and 7-aminoclonazepam are confirmed in the benzodiazepine analysis, 7-aminoclonazepam can be reported without an additional confirmatory test for 7-aminoclonazepam. Similarly, if screening results or initial testing indicate the presence of a metabolite, and further testing confirms the presence of the drug and its metabolite(s), the drug and its metabolites(s) may be reported as identified. For example, if 11-nor-9-carboxy- Δ^9 -tetrahydrocannabinol (THC-COOH) is indicated by an immunoassay screen, and both THC-COOH and Δ^9 -tetrahydrocannabinol (Δ^9 -THC) are confirmed in a single sampling used for the cannabinoid analysis, both Δ^9 -THC and THC-COOH may be reported without an additional confirmatory test for Δ^9 -THC.

- Situations may also occur where both a drug and metabolite are indicated in a drug screen, yet only the drug or its metabolites is confirmed in the second test. As long as confirmatory testing is not negative for the drug and/or metabolite, both may be reported as positive. For example, if zolpidem and its metabolite are indicated in an alkaline drug screen, and zolpidem is confirmed via a method that is not designed to look for the metabolite (such as the alkaline drug quantitation), both may be reported without an additional confirmatory test for the zolpidem metabolite.
- The decision criteria were met for the procedure(s) that gave positive results.
- Mass spectrometry has been used as part of the testing procedure.
- Use the word “detected” to report positive results if any of the following apply:
 - Positive results are obtained for a mass spectrometric method for an analyte in one sampling of a biological specimen but there is not enough sample left to perform a second confirmatory analysis.
 - Positive results are obtained for a mass spectrometric method for an analyte in one sampling of a biological specimen but the case scenario does not warrant further analysis.
 - No certified reference material is available for mass spectral

comparison but the mass spectral results compare favorably to a library entry.

- Use the word “inconclusive” to report unconfirmed results if immunoassay screening results are positive but there is insufficient sample remaining for a second confirmatory analysis.
- Use the phrase “not detected” to report negative results when the results of a screening and/or confirmatory procedure are negative.

Additionally, results can be reported as “not detected” if something detected in a screen is not considered to be probative and subsequently the sample(s) are not subjected to confirmatory analysis.

- d. The **Limitations** section will be used to communicate any known limitations of the results, or limitations of the testing based on the evidence received. Examples of appropriate wording for the **Limitations** section are included in Appendix 3.

- When general alkaline and/or acid/neutral screens are performed on a sample, state that many drugs/metabolites were screened for, and that the lab may be contacted if a particular drug or metabolite of interest is not mentioned in the report.
- If testing was limited based on the amount of time between an incident and the specimen collection, include an explanation.
- If testing was limited based on the amount of specimen received, state this.
- The limitations of an ethanol back-extrapolation are stated (see TOX109).
- Additional information may be found in toxicology’s Approved Standards for Scientific Testimony and Report language (ASSTR).

- e. The **Remarks** section will include requirements set forth in the *FBI Laboratory Operations Manual*.

The **Remarks** section may also include facts and interpretations to assist the reader. Examples of appropriate wording for the **Remarks** section are included in Appendix 4.

The following may be included in the **Remarks** section when applicable and appropriate, and when this information may assist the reader of the report.

- Trade names, drug class, uses, side effects, metabolism and/or Federal Schedule of drugs mentioned in the **Results of Examinations** section

- Interpretation of a reported drug concentration
 - When published antemortem blood drug concentrations are used to interpret postmortem blood drug concentrations, this will be noted in the **Remarks** section.
 - An explanation of how to properly collect, mark and preserve toxicology specimens in the future
- f. Maintain copies of approved reports in a central location in order to facilitate consistency over time and among examiners.
- g. When the words “detected” or “inconclusive” are used in the **Results of Examinations** section of a laboratory report, define them in the **Remarks** section as follows:
- An analyte(s) has been reported as *detected* in this report due to insufficient sample volume and a second confirmatory analysis could not be performed for that analyte(s).
 - An analyte(s) has been reported as *detected* in this report since further analyses were not warranted based on the case scenario.
 - An analyte(s) has been reported as *detected* in this report because the Laboratory does not have a certified reference material for comparison.
 - An analyte(s) has been reported as *inconclusive* in this report because preliminary screening results indicated the possible presence of this analyte but confirmatory analysis could not be performed due to insufficient specimen volume.

7 Calculations

Not applicable.

8 Measurement Uncertainty

Not applicable.

9 Limitations

Not every scenario can be anticipated. This document serves as a general guideline only

10 Safety

Not applicable.

11 References

FBI Laboratory Practices for the Formatting and Content of a Report of Examination - Legacy,
FBI Laboratory Operations Manual

Practices for Preparing Reports of Examination and Retaining Records in Forensic Advantage
(FA), FBI Laboratory Operations Manual

FBI Laboratory Toxicology Approved Standards for Scientific Testimony and Report Language
(ASSTR)

Rev. #	Issue Date	History
4	03/01/16	Removed Calibration Section (5) and renumbered subsequent sections. In Section 6.a., clarified that interpretations are needed only when applicable. Changed reference to Lab Ops Manual in Section 6.b. and Section 6.e. in order to be generic and updated references in Section 11 to cover Legacy and Forensic Advantage Reports. In Section 6.c., situations involving reporting of a drug and metabolite were added for clarification. In Section 6.c, clarified wording for rounding of uncertainty values. In Section 6.c, changed reporting option for non-probative, non-confirmed analytes from “detected” to “not detected”. In Sections 6.c and 6.g, removed LCUV example since this testing is no longer performed. Also clarified “not detected” example wording in Section 6.g. In Section 6.e., added a comment about interpreting postmortem blood concentrations based on published antemortem blood concentrations. Renamed Section 8. In Appendices 1-3, replaced references to “Q” numbers with “Item” numbers.
5	04/01/19	Section 2: Updated scope statement. Section 6-d: added some specifics to the limitations wording. Removed “subunit” in multiple instances. In Section 6-c, added bullet point that allows for case scenario related use of “detected”. Section 11: added reference to ASSTR. Removed a statement from Appendix 3.

Approval

Redacted - Signatures on File

Toxicology
Technical Leader:

Date: 03/28/2019

Chemistry Unit Chief:

Date: 03/28/2019

QA Approval

Quality Manager:

Date: 03/28/2019

Appendix 1: Example of a Results Summary

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Appendix 2: Example of Appropriate Wording for the Results of Examinations Section of a Toxicology Report

The Item 1 blood was tested with the following results:

<u>Analyte</u>	<u>Result</u>	<u>Note(s)</u>
Ethanol	Item 1 = Ethanol was identified at a concentration of 0.119 ± 0.017 gram percent (g%) (99.7% confidence level, k=3).	1
Benzodiazepines	Item 1 = Not detected	2
Cannabinoids (Δ^9 -THC metabolite)	Item 1 = Not detected	2
Benzoylcegonine (a metabolite of cocaine)	Item 1 = Not detected	2
Over-the-counter, prescription and illicit drugs	Item 1 = Not detected	3

Notes:

- 1 Analysis was performed using headspace gas chromatography with flame ionization detection (HS-GC/FID) and headspace gas chromatography/mass spectrometry (HS-GC/MS).
- 2 Analysis was performed using immunoassay.
- 3 This analysis consisted of two drug screens. The first screen targeted alkaline drugs such as antihistamines, antidepressants, opioid analgesics, methamphetamine and other stimulants. Analysis was performed using solid phase extraction (SPE) followed by gas chromatography/mass spectrometry (GC/MS) and liquid chromatography/mass spectrometry (LC/MS). The second screen targeted acidic and neutral drugs such as barbiturates, seizure medications, and some non-steroidal anti-inflammatory drugs. Analysis was performed using liquid/liquid extraction (LLE) followed by GC/MS.

Appendix 3: Examples of Appropriate Wording for the Limitations Section of a Toxicology Report

Example of a statement to explain general drug screen limitations:

The FBI Laboratory has performed screening in this case for numerous drugs, some of which are only indicated by a general drug class above. Drug dosages, drug metabolism rates, and laboratory detection limits for drugs and metabolites vary. For questions about whether or not a specific drug or drug metabolite would have been detected in this analysis, please contact the examiner issuing this report.

Example of a statement to explain why testing was limited based on time lag between incident and specimen collection:

Due to the time that elapsed between the alleged event and the collection of the Item1 urine specimen, the Item1 urine specimen was not tested for gamma-hydroxybutyrate (GHB) or ethanol, two drugs commonly associated with drug-facilitated assaults. GHB and ethanol are rapidly metabolized and excreted from the body, and are typically not detected beyond eight to twelve hours post-ingestion.

Example of a statement to explain that limited specimen precluded a complete toxicological analysis:

Testing in this case was limited to ethanol analysis due to the low volume of specimen Item1 received.

Appendix 4: Examples of Appropriate Wording for the Remarks Section of a Toxicology Report

Example of a drug information statement:

Oxycodone is a schedule II federally controlled substance. Oxycodone is available by prescription by itself, or in combination with other drugs such as acetaminophen or aspirin. Oxycodone is classified as an opioid analgesic, and may be prescribed for severe pain. Common trade names of oxycodone include Oxycontin[®] and Percocet[®]. The reported blood concentration of oxycodone (20 µg/mL) is consistent with reported cases of oxycodone fatalities.

Example of a statement on how to properly preserve and mark toxicology specimens in the future:

In the future, when toxicology testing is requested in postmortem investigations, the FBI Laboratory recommends that two grey-top tubes of blood be submitted for analysis, as grey-top tubes contain both a preservative and an anticoagulant. It is also requested that the source of that blood (central or peripheral) is specified, to aid in the interpretation of quantitative results. Additionally, the FBI Laboratory recommends the submission of a second biological specimen such as urine or vitreous humor to allow for thorough screening and to aid in the interpretation of positive results.